URGENT Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

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To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Monitor B20/B40 V1, B30 and B40 V2 intermittent ECG filter issue**

GE Healthcare has recently become aware of a potential safety issue due to ECG filter settings associated with the B20/B40 V1, B30 and B40 V2 Patient Monitors. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The B20, B30 and B40 Patient Monitors set the ECG filter setting incorrectly if the monitor starts with impedance respiration set in the ON position. Instead of the user selected filter, an additional 0.5 Hz high pass filter is used. The additional 0.5 Hz high pass filter causes changes to the ECG waveform morphology and incorrect display of ST values. The ST-elevation measurement can be under estimated in this situation and therefore the treatment of the patient can be delayed.

There is no issue when the monitor starts with impedance respiration set in the OFF position.

Safety Instructions

In order to avoid incorrect filter settings, you need to save impedance respiration to be OFF as the default by following these instructions:

1. Turn on the monitor
2. If you have "Resp" displayed on the Waveform Field, turn OFF "Resp" in Waveform Fields (Monitor Setup->Screen Setup->Waveform Fields->Field); If you have "Resp" displayed on the Digit Field, turn OFF "Resp" in Digit Fields (Monitor Setup->Screen Setup->Digit Fields->Field).
3. Save this mode. (Monitor Setup->Install/Service(16,4,34)->Save Modes(13,20,31)
4. Turn off the monitor

Note 1: the settings are mode related, the above procedure must be repeated when the mode is changed.

Each time you need the impedance respiration parameter, follow the below instructions before initiating patient monitoring:

1. Reboot the monitor and make sure the monitor starts with impedance respiration OFF.
2. Turn ON impedance respiration

Note 2: for B30, don't reconnect the E-PSM(P)W or E-PSM(P) module when using the impedance respiration parameter, only change the E-PSM(P)W or E-PSM(P) module when the monitor is turned OFF.

Affected Product

The issues described above may occur in the following product software versions:

- B20 V1: VSP-A_1.13 and earlier (unit SN range: SGF11030001WA ~ SGF13176741WA).

Details

- B40 V1: VSP-A_1.13 and earlier (unit SN range: SG211210001WA ~ SG213172146WA).
- B40 V2: VSP-B 1.02 and earlier (unit SN range: SJF13010005WA ~ SJF13180144WA).
- B30: L-DICU08.2.1.9 and earlier (unit SN range: SF309380033WA ~ SF313177120WA).

Product Correction

Please retain a copy of these instructions with the user manual for your B20, B30 or B40 Patient Monitors. GE Healthcare will provide a correction at no charge once it is available. We will contact you to arrange for this correction.

Contact Information

If you have any questions regarding this notification, please contact Technical Support or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

[redacted]
Vice President QARA
GE Healthcare Systems

[redacted]
Chief Medical Officer
GE Healthcare